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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,538	06/27/2003	Caius Rommens	058951-0167	5766

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EXAMINER	
FOX, DAVID T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,538	ROMMENS ET AL.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5,13 and 44-57* is/are pending in the application.

4a) Of the above claim(s) *56 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5,13 and 44-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/25/04 & 9/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS 10/12/05 & 2/22/06*.

Applicant's election without traverse of Group I in the reply filed on 02 March 2006 is acknowledged.

Claims 3, 5, 13 and 44-55, corresponding to Group I as set forth in the Restriction Requirement mailed 14 February 2006, are hereby examined. Claims 56-57 are withdrawn as being drawn to a non-elected invention.

The effective filing date for the instantly claimed invention is 20 February 2002, the earliest provisional application, which discloses all aspects of the claimed invention.

The application should be reviewed for errors. Errors appear, for example, in claim 53, line 2, where "facilitates" should be replaced with ---facilitate---.

In addition, the specification is objected to for the following errors and omissions. All specification amendments should comply with 37 CFR 1.121(b).

Page 2 of the specification, paragraph [0001], should be amended to insert the filing dates of each provisional application.

Tables 10 and 11, found on pages 119-120 and 122-123, are objected to for their inclusion of shaded material which obliterates the text, and which will not be reproduced faithfully. Applicant is requested to resubmit these tables with no shaded rows.

Page 20, paragraph [0047], and page 58, paragraph [0215], are objected to for their designation of SEQ ID NO:34 as comprising wheat sequences. However, the Sequence Listing characterizes SEQ ID NO:34 as a potato sequence (see, e.g., page 154 of the specification). Clarification is requested. New matter should be avoided.

Page 36, paragraph [0120], is objected to for its designation of SEQ ID NOS:94 and 95 as potato-derived P-DNA borders. However, the Sequence Listing

characterizes these sequences as being derived from wheat (see, e.g., page 154 of the specification). The Sequence Listing also characterizes SEQ ID NOS: 54 and 55 as potato-derived P-DNA borders (see, e.g., page 60 of the specification, Table 2; and page 154 of the specification). Clarification is requested. New matter should be avoided.

On page 129, line 1, "toxic" is recited twice.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 5, 13, 44-49 and 51-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 177-189, 192, 195 and 197-198 of copending Application No. 10/369,324. Although the conflicting claims are not identical, they are not patentably distinct from each other

because it would have been obvious to one of ordinary skill in the art to utilize the method of plant transformation with a plant sequence which is integrated into the genome of the plant, and plant transformation with a marker gene sequence which is not integrated into the plant genome, wherein said transformation of the plant sequence does not involve T-DNA, wherein Agrobacterium is used to effect transformation, wherein binary vectors and single or multiple Agrobacterium strains are utilized, wherein the plants may be monocots or dicots, wherein a cytokinin gene including the ipt gene is used as a backbone integration marker gene, wherein the transformed plant exhibits improved disease resistance, storage characteristics, color or starch content; and the resultant plants; as claimed in the copending application; to obtain the method of plant transformation with a plant sequence which is integrated into the genome of the plant, and plant transformation with a marker gene sequence which is not integrated into the plant genome, wherein said transformation of the plant sequence does not involve T-DNA, wherein Agrobacterium is used to effect transformation, wherein binary vectors and single or multiple Agrobacterium strains are utilized, wherein the plants may be monocots or dicots, wherein a cytokinin gene including the ipt gene is used as a backbone integration marker gene, wherein the transformed plant exhibits down-regulation of the R1, polyphenol oxidase, or phosphorylase genes, which plant would inherently exhibit improved disease resistance, storage characteristics, color or starch content; and the resultant plants; as claimed in the instant application. The claims are coextensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 3, 5, 13, and 44-53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 10/505,079. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the method of plant transformation with a plant sequence which is integrated into the genome of the plant, and plant transformation with a marker gene sequence which is not integrated into the plant genome, wherein said transformation of the plant sequence does not involve T-DNA, wherein Agrobacterium is used to effect transformation, wherein binary vectors and single or multiple Agrobacterium strains are utilized, wherein the plants may be monocots or dicots, wherein a codA (cytosine deaminase) gene is used as a negative selectable marker, wherein the transformed plant exhibits improved disease resistance, storage characteristics, color or starch content; and the resultant plants; as claimed in the copending application; to obtain the method of plant transformation with a plant sequence which is integrated into the genome of the plant, and plant transformation with a marker gene sequence which is not integrated into the plant genome, wherein said transformation of the plant sequence does not involve T-DNA, wherein Agrobacterium is used to effect transformation, wherein binary vectors and single or multiple Agrobacterium strains are utilized, wherein the plants may be monocots or dicots, wherein a codA (cytosine deaminase) gene is used as a negative selectable marker,

wherein the transformed plant exhibits down-regulation of the R1, polyphenol oxidase, or phosphorylase genes, which plant would inherently exhibit improved disease resistance, storage characteristics, color or starch content; and the resultant plants; as claimed in the instant application. The claims are coextensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim is drawn to a progeny plant produced by crossing a hemizygous transgenic plant with itself or a non-transformed plant (see claim 3, part (3)). Due to Mendelian segregation of the transgene, some of the progeny plants will have lost the transgene, and will thus be indistinguishable from naturally occurring plants. Accordingly, the claim is drawn to products of nature, which are not statutory subject matter.

Amendment of claim 13 to indicate that the progeny plants contain the desired polynucleotide in their genome, as recited in step (4) of claim 3, would obviate this rejection.

See American Wood v. Fiber Distintegrating Co., 90 U.S. 566 (1974), American Fruit Growers v. Brogdex Co., 283 U.S. 2 (1931), Funk Brothers Seed Co. v. Kalo Inoculant Co., 33 U.S. 127 (1948), Diamond v. Chakrabarty, 206 USPQ 193 (1980).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-50 and 54-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claims 44 and 46 are confusing in their recitation of "transfer-DNAs" and "transfer-DNA", respectively, since the claims depend upon claim 3 which prohibits the use of T-DNA. Furthermore, the term "transfer DNA" is not explicitly defined in the specification. If intended, replacement of "transfer-DNAs" and "transfer-DNA" in claims 44 and 46 with ---carrier DNAs--- and ---carrier DNA---, as recited on page 60 of the specification, paragraph [0219], would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5, 13 and 44-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to plant transformation with "sequences that are native to the genome of the plant cell", wherein such sequences may

be of any length and sequence and from any plant species or gene source (see, e.g., claim 3, part 2); wherein such sequences may be in any "transfer-DNA" of any length and sequence (see, e.g., claim 44); or wherein such sequences may be any P-DNA of any length and sequence and from any plant (see, e.g., claim 46). The specification defines "P-DNA" borders as being 5-100 base pairs in length, including those sequences with as little as 50% similarity to T-DNA borders, and including those mutated or variant sequences with less than 50% similarity to the initially isolated P-DNA border sequence (see, e.g., page 18 of the specification, paragraph [0043]; page 58, paragraphs [0214] and [0215]; pages 65-66, paragraph [0235]).

In contrast, the specification only demonstrates the isolation of two P-DNA border sequences from the single plant species of potato, which border sequences are 25 base pairs long, and comprise SEQ ID NOS: 54 and 55 (see, e.g., page 60, Table 2, bottom two rows). No guidance has been presented for any other "transfer DNA" or "native plant genomic sequences" from any other plant species, of any other length or sequence, or any variants thereof; or plant transformation therewith.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the

absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and

plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claims 3, 5, 13 and 44-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to methods of using P-DNA borders from potato, comprising SEQ ID NOS: 54 and 55, to integrate desired polynucleotides into the potato plant genome, and to the resultant transformed potato plants; does not reasonably provide enablement for claims broadly drawn to the use of any plant polynucleotide of any length and sequence for the transformation of any plant species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to plant transformation with "sequences that are native to the genome of the plant cell", wherein such sequences may be of any length and sequence and from any plant species or gene source (see, e.g., claim 3, part 2); wherein such sequences may be in any "transfer-DNA" of any length and sequence (see, e.g., claim 44); or wherein such sequences may be any P-DNA of any length and sequence and from any plant (see, e.g., claim 46). The specification defines "P-DNA" borders as being 5-100 base pairs in length, including those sequences with as little as

50% similarity to T-DNA borders, and including those mutated or variant sequences with less than 50% similarity to the initially isolated P-DNA border sequence (see, e.g., page 18 of the specification, paragraph [0043]; page 58, paragraphs [0214] and [0215]; pages 65-66, paragraph [0235]).

In contrast, the specification only demonstrates the isolation of two P-DNA border sequences from the single plant species of potato, which border sequences are 25 base pairs long, and comprise SEQ ID NOS: 54 and 55 (see, e.g., page 60, Table 2, bottom two rows); wherein potato or tobacco plants were transformed therewith. No guidance has been presented for any other "transfer DNA" or "native plant genomic sequences" from any other plant species, of any other length or sequence, or any variants thereof; or plant transformation therewith. Moreover, no guidance has been provided for the transformation of plant species other than the related potato and tobacco, both of the *Solanaceae* family.

Plant transformation with plant-derived "border-like" sequences is unpredictable. P-DNA borders isolated from *potato* actually gave *higher* overall transformation frequency, as well as *higher* frequency of marker-free transformants containing only the gene-of-interest, when introduced into *tobacco* plants, which are not sexually compatible with potato (see, e.g., page 152 of the specification, Table 16). See pages 131-132 of the specification, paragraphs [0400] and [0401], where it is taught that the vector comprising the desired gene-of-interest comprises P-DNA borders.

Furthermore, P-DNA is much less efficient than T-DNA as a means of integrating desired nucleotides into the plant genome, wherein said plants are also marker-free. Compare Table 12, page 148, first row (wherein the vector containing the desired gene-of-interest comprises T-DNA borders, as taught on pages 125-126 of the specification, paragraphs [0383] and [0385])); with Table 14, page 150 (wherein the vector comprising the desired gene-of-interest comprises P-DNA borders, as taught on pages 127-128 of the specification, paragraph [0389]). A ten-fold increase in transformants which contain only the gene-of-interest was observed in potato plants transformed with T-DNA borders enclosing the gene-of-interest. See also page 128 of the specification, top paragraph, last two sentences.

The function of variants of the P-DNA borders with less than 50% sequence similarity thereto, as contemplated on pages 65-66 of the specification, paragraph [0235], is unpredictable and unlikely. See page 94 of the specification, last four sentences of the top paragraph, where it is taught that highly variant T-DNA borders are non-functional.

Finally, the efficiency of recovery of transformed marker-free plants which contain only the gene-of-interest is low, as discussed above. Appreciable recovery of said marker-free transformed plants only occurs when the "LifeSupport" vector, which comprises the selectable marker gene bounded by T-DNA borders, also contains either a negative selectable marker gene to select against the persistence of the original selectable marker gene,

or a mutated *virD2* gene to inhibit genomic integration of the selectable marker gene (see, e.g., Table 14, page 150, versus Table 15, page 151. See also Examples 12-13 of the specification, pages 128-131, and Figure 5).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified P-DNAs or "transfer-DNAs" of a multitude of lengths and sequences, from a multitude of plant species and genomic regions. Undue experimentation would have also been required to evaluate said non-exemplified sequences, or a multitude of sequence variants or fragments of the exemplified or non-exemplified P-DNA sequences, for their ability to effect marker-free integration of a desired gene-of-interest into the genome of a multitude of non-exemplified or exemplified plant species.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3, 5, 13 and 51-52 are rejected under 35 U.S.C. 102(e) as being anticipated by McElroy et al (US Patent 6,750,379 effectively filed 09 March 2000).

The claims are broadly drawn to a method of plant transformation with "desired polynucleotides" (which comprise sequences native to the genome of the transformed plant) and a selectable marker gene, wherein the transformants comprise the desired polynucleotides, wherein the transformants are selfed or cross-fertilized to produce progeny plants, and wherein progeny plants are identified which comprise the desired polynucleotide but do not comprise the marker gene, and wherein T-DNA is not employed to transfer the desired polynucleotide to the plant genome. The claims are also drawn to the resultant transformed plants, which may be monocots or dicots, and to methods where the marker gene is an antibiotic or herbicide resistance marker gene, wherein the marker gene may be expressed for 1-10 days.

McElroy et al teach the desirability of obtaining transformed plants without the use of T-DNA and wherein selectable marker genes are not integrated into the plant genome or transmitted to transformed progeny plants, wherein said plants are obtained by particle bombardment-mediated maize plant transformation with a construct comprising the maize HSP70 intron and a CryIA insect-resistance gene-of-interest, wherein said transforming construct also comprises selectable marker genes comprising the kanamycin resistance gene or the *bar* gene conferring herbicide resistance, wherein progeny plants are obtained by crossing the transformed plants, and wherein progeny plants are identified which contain only the desired gene-of-interest conferring the agronomic trait of insect resistance, wherein said progeny plants also comprising the maize HSP70 intron sequences. McElroy et al also suggest the use of genes-of-interest which confer disease resistance or improved starch quality or

improved appearance; and also suggest the use of sense or antisense plant coding sequences as the gene-of-interest, and plant promoters; including maize coding sequences and maize promoters for maize transformation (see, e.g., Figures 4-5 and 9-13; column 1, line 51 through column 2, line 29; column 2, line 65 through column 5, line 19; column 7, lines 31-40 and 52-57; column 10, lines 10-22 and lines 44-58; column 11, lines 1-11 and 27-36; column 12, lines 6-10, 21-23 and 47-64; column 17, line 49 through column 18, line 16; column 30, lines 17-23 and 32-51; column 31, lines 8-13 and 30-35; column 33, lines 25-36; column 39, lines 20-32 and 55-67; column 42, lines 1-54; column 44; column 47, line 32 through column 48, line 39; column 65, line 45 through column 69, line 55; column 70, lines 35-40; claims 1-3 and 5-14).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 5, 13 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over McElroy et al (US 6,750,379 effectively filed 09 March 2000) in view of each of Lorberth et al (1998, Nature Biotechnology, Applicant submitted) and WO 94/03607 to KEYGENE (Applicant submitted).

The claims are broadly drawn to a method of plant transformation with "desired polynucleotides" (which comprise sequences native to the genome of the transformed plant) and a selectable marker gene, wherein the transformants comprise the desired polynucleotides, wherein the transformants are selfed or cross-fertilized to produce progeny plants, and wherein progeny plants are identified which comprise the desired polynucleotide but do not comprise the marker gene, and wherein T-DNA is not employed to transfer the desired polynucleotide to the plant genome. The claims are also drawn to the resultant transformed plants, which may be monocots or dicots, and to methods where the marker gene is an antibiotic or herbicide resistance marker gene, wherein the marker gene may be expressed for 1-10 days. Claim 53 is drawn to a method wherein the desired polynucleotide down-regulates the expression of R1, polyphenol oxidase, or phosphorylase.

McElroy et al teach a method of plant transformation with desired polynucleotides comprising a gene-of-interest and nucleotide sequences native to the genome of the plant to be transformed, wherein the resultant transformed plants are selfed or crossed to produce progeny plants which do not comprise a selectable marker gene, as discussed above. McElroy et al also suggest the use of genes-of-interest which confer improved starch properties, physical appearance, or disease resistance to plants

transformed therewith; wherein the genes-of-interest may be in antisense orientation to down-regulate genes native to the plant species to be transformed, as discussed above. McElroy et al also suggest the transformation of a variety of plants including potato (see, e.g., column 7, line 36-41).

McElroy et al do not explicitly teach plant transformation with genes-of-interest which down-regulate the R1, PPO, or phosphorylase genes.

Lorberth et al teach potato plant transformation with an antisense construct which down-regulates the R1 protein expression, causing improved starch quality and decreased tuber sweetening in cold storage (see, e.g., page 473, column 2, middle paragraph; page 475, Table 1 and paragraph bridging the columns, first full paragraph of column 2; page 478, column 1, middle paragraph).

KEYGENE teaches that potato transformation with an antisense construct to the polyphenol oxidase gene results in decreased bruising (see, e.g., Figures 2-4; page 1, middle paragraph through page 3, top paragraph; page 9; page 11, bottom paragraph through page 12, second full paragraph; page 12, bottom paragraph through page 16, top paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the method of plant-derived polynucleotide sequence-mediated transformation to obtain marker-free transformed plants as taught by McElroy et al, and to modify that method by incorporating potato plants as the transformant and either the R1 or PPO antisense constructs for improvement of starch quality or stored tuber appearance as taught by either Lorberth et al or KEYGENE, as suggested by McElroy.

Claims 44-50 and 54-55 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest methods of plant transformation which use *Agrobacterium* but which do not employ T-DNA during the transformation process.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 15, 2006

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638